K02 3687

SIEMENS

510(k)

NOV 2 2 2002

Attachment 1

Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information

Device Name:	SOMATOM Emotion 6 Computed Tomography X-ray Systems
Classification Name:	§ 892.1750: Computed tomography X-ray system
Proprietary Trade Name:	SOMATOM Emotion 6
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Registration Number:	2240869
Address:	Siemens Medical Systems, Inc. 186 Wood Avenue South Iselin, N.J. 08830
Contact Person:	Praveen Nadkarni Technical Specialist, Regulatory Submissions (732) 321-4950

Date of Summary Preparation: 10/29/02

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description:
The Siemens SOMATOM Emotion 6 systems are a whole body X-ray computed tomography scanners, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

Intended Use:

The SOMATOM Emotion 6 systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

Technological Characteristics:
The SOMATOM Emotion 6 systems are whole body X-ray computed tomography scanners, which features a continuously rotating tube-detector system and functions according to the fan beam principle. The systems are based on the existing SOMATOM Emotion systems (for further details see chapter 2). The system will operate with SOMARIS/5 software.

General Safety and Effectiveness Concerns:
All components of the SOMATOM Emotion 6 systems subject to the Federal Diagnostic Equipment Performance Standard and applicable regulations of 21CFR § 1020.30 and § 1020.33 are certified to meet those requirements; and an initial report as per 21 CFR § 1002.10 will be filed with the Center for Devices and Radiological Health (CDRH). To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice. The SOMATOM Emotion Duo is designed to meet the ELECTRICAL AND MECHANICAL SAFETY STANDARD IEC 60601-1 and UL 187 X-RAY EQUIPMENT STANDARD FOR SAFETY.

Substantial Equivalence:
Siemens believes that within the meaning of the Safe Medical Device Act of 1990, the SOMATOM Emotion 6 systems operating with SOMARIS/5 software are substantially equivalent to the Siemens SOMATOM Emotion Duo and Somatom Sensation 4 CT scanners in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

Mr. Praveen Nadkarni
Technical Specialist,
Regulatory Submissions
SIEMENS Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K023687
Trade/Device Name: SOMATOM Emotion 6 CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: October 29, 2002
Received: November 1, 2002

Dear Mr. Nadkarni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indication for use

510(k) Number (if known): K023687

Device Name: SOMATOM Emotion 6 systems

Indication for use:

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(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

Prescription Use ✓

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023687